14

Claims

- 1. A method of treating a human body having cancer comprising administering an effective therapeutic amount of ET-743 in combination with an effective therapeutic amount of 5-fluorouracil or a pro-drug thereof.
- 2. The method according to claim 1, wherein ET-743 is administered in combination with a 5-fluorouracil pro-drug.
- 3. The method according to claim 2, wherein ET-743 is administered in combination with capecitabine.
- 4. The method according to claim 3, wherein capecitabine and ET-743 are provided as separate medicaments for administration at different times.
- 5. The method according to claim 4, wherein capecitabine is administered in a dose range between 1500 to 2500 mg/m²/day.
- 6. The method according to claim 4, wherein ET-743 is administered in a dose range between 0.75 and 1.4 mg/m^2 .
- 7. The method according to claim 5 or 6, wherein capecitabine is administered in a dosage of up to 2000 $mg/m^2/day$ and ET-743 is administered in a dosage of up to $1.2 mg/m^2$.

15

- 8. The method according to claim 7, wherein capecitabine is administered in a dosage about 1600 mg/m²/day and ET-743 is administered in a dosage about 0.9 mg/m².
- 9. The method according to claim 5 or 6, wherein capecitabine is orally administered.
- 10. The method according to claim 9, wherein ET-743 is administered by intravenous injection.
- 11. The method according to claim 10, wherein the infusion time for intravenous injection of ET-743 is up to 24 hours.
- 12. The method according to claim 11, wherein the infusion time for intravenous injection of ET-743 is about 3 hours for ET-743.
- 13. The method according to claim 10, where the infusions of ET-743 are carried out at an interval of 1 to 6 weeks.
- 14. The method according to claim 13, wherein the infusion of ET-743 is carried out once every 21 days.

16

- 15. The method according to claim 14, wherein the infusion of ET-743 is carried out on day 1 and the administration of capecitabine from days 2 to 15, every 21 days.
- 16. The method according to claim 15, wherein capecitabine is administered twice-daily.
- 17. A method according to any preceding claim, in which the patient has a cancer selected from sarcoma, osteosarcoma, ovarian cancer, breast cancer, melanoma, vaginal cancer, colorectal cancer, gastric cancer, adenocarcinoma, mesothelioma, renal cancer, endometrial cancer and lung cancer.
- 18. A method according to claim 17, in which the patient has a cancer selected from sarcoma, breast cancer, gastric cancer, vaginal cancer and adenocarcinoma.
- 19. The use of ET-743 in the preparation of a medicament for a method according to any of claims 1 to 18.
- 20. The use of 5-fluorouracil or a pro-drug thereof in the preparation of a medicament for a method according to any of claims 1 to 18.
- 21. A medical kit for administering ET-743 in combination with capecitabine, comprising a supply of ET-743 in dosage units for at least

17

one cycle, wherein each dosage unit contains the appropriate amount of ET-743 for the treatments and a pharmaceutically acceptable carrier, and printed instructions for administering ET-743 according to a dosing schedule.